

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

Cullen & Co
GPO Box 1074
BRISBANE QLD 4001

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) 5 OCT 2004

Applicant's or agent's file reference
030821PCGCIJ

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/AU2004/001012

International filing date (day/month/year)
30 July 2004

Priority date (day/month/year)
31 July 2003

International Patent Classification (IPC) or both national classification and IPC

☐ Cl. ⁷ A61M 25/06, 5/32

Applicant

MEDIGARD LIMITED et al

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU
AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address: pct@ipaaustralia.gov.au
Facsimile No. (02) 6285 3929

Authorized Officer

STEPHEN CLARK
Telephone No. (02) 6283 2781

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/AU2004/001012

Box No. I

Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/AU2004/001012

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
- ☐ paid additional fees
- ☐ paid additional fees under protest
- ☐ not paid additional fees
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
- ☒ not complied with for the following reasons:

Claims 1-16 relate to a cannula/catheter introducer with inner and outer tubular members, sealing means, release means, a needle holder with a release means where movement of the inner tubular member allows the release means to lock against the needle release means and vacuum retract the needle.

Claim 17 relates to a cannula/catheter introducer with inner and outer tubular members, retraction means for a puncture needle and a limit means to limit the travel of the inner tubular member, located adjacent a distal end of the introducer.

The only technical features of the claims that are common are the catheter/cannula introducer, the inner and outer tubular members and retraction of a needle. These features are common to this art and found in the "A" category citations of the ISR. The remaining special technical features are not shared by both sets of claims and as such the claims lack unity a posteriori.

4. Consequently, this opinion has been established in respect of the following parts of the international application:
- ☒ all parts
- ☐ the parts relating to claims Nos.

**WRITTEN OPINION OF THE
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International application No.

PCT/AU2004/001012

Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|-----|
| Novelty (N) | Claims 1-17 | YES |
| | Claims | NO |
| Inventive step (IS) | Claims 1-17 | YES |
| | Claims | NO |
| Industrial applicability (IA) | Claims 1-17 | YES |
| | Claims | NO |

2. Citations and explanations:



Novelty (N), Inventive Step (IS) Claims 1-17

None of the citations alone, or in obvious combination, disclose all of the features of any of the claims.

In particular, the features of claims 1-16 where inner and outer tubular members are present and movement of the inner tubular member allows the release means to lock against the needle release means to vacuum retract the needle was not found.

The limit means adjacent the distal end of the introducer to limit the travel of the inner tubular member of claim 17 was also not found.

